

**केन्द्रीय मुहर विभाग-2**

संदर्भ -: केमूवी-2/16:758

27 10 2023

**विषय: संशोधित IS 758:2023 के अनुपालन के दिशा निर्देश**

यह उपरोक्त विषय के संदर्भ में है।

सक्षम अधिकारी द्वारा अनुमोदित दिशानिर्देश अनुपालन हेतु संलग्न है।

सभी क्षेत्रीय/शाखा कार्यालयों से अनुरोध है की दिशानिर्देशों का तत्काल प्रभाव से अनुपालन सुनिश्चित करें।

**आदित्य दास  
वैज्ञानिक D**

**प्रमुख (केमूवी 2)**

**सभी क्षेत्रीय/शाखाकार्यालय/प्रयोगशालाएँ/TXD/LRMD**

**CENTRAL MARKS DEPARTMENT-2**

Our Ref: CMD-2/16:758

27 10 2023

**Subject: Guidelines for implementation of Revised IS 758:2023**

This has reference to the subject mentioned above.

The Competent Authority has approved the enclosed Guidelines for implementation.

All ROs/BOs are requested to ensure the implementation of the above Guidelines with immediate effect.

**(Aditya Das)  
Scientist D**

**Head (CMD-2)**

**All ROs/BOs/Labs/TXD/LRMD**

## CENTRAL MARKS DEPARTMENT-2

Our Ref: CMD-2/16: 758

27 10 2023

### **Subject: Guidelines for implementation of Revised IS 758:2023 (Medical Textiles — Absorbent Cotton Gauze — Specification)**

1. IS 758:1988 has been revised as IS 758:2023 and has been published. The last date for implementation of the revised Standard is **28 March 2024** after which the old Standard shall stand withdrawn.
2. All BOs shall inform the Applicants and Licensees under their jurisdiction about implementation of the revised Standard within a week of issuance of these guidelines.
3. The significant changes in the revised Standard as listed in the Table are given for the purpose of general guidance. BOs shall ensure that the product conforms to all the requirements, as applicable, as per the revised Standard.

Clause No.	Change
1	Title and scope of the standard has been updated (non-sterilized has been removed)
2.2	Requirement for cloth has been modified (Definition of cotton absorbent gauze and fabric defects has been updated)
4.1	Fibre identification test has been specified;
4.2, Table 1 S.No. (x)	Sterility test (optional) has been specified;
2, Annex A	References to Indian Standards have been updated;
5 and 6	BIS certification marking clause and Marking and packing clauses has been updated
7	Sampling and criteria of conformity has been modified.

4. Consequent upon the issuance of the revised Standard, the existing product manual has been revised which is being circulated separately.
5. The guidelines for implementation of the revised Standard is given below:

#### **A. LICENSEES:**

- i. The licensee shall implement the revised Standard by **28 March 2024**. Any difficulty in implementation shall be brought to the notice of CMD 2 at the earliest. BOs shall ensure that no Licences are under operation as per the old Standard after **28 March 2024**. **The status of implementation of the revised Standard shall be confirmed by Head (BO) to CMD-2 within two weeks of the last date of concurrent running.**
- ii. The licensee shall submit evidence of conformity to the additional/modified requirements through In-house/Independent Test Reports. Verification of implementation of the revised Standard, wherever required, **shall be verified through a surveillance visit within 30 days of confirmation of implementation of the revised standard by licensee.**

- iii. If the Licensee fails to complete all actions by **28 March 2024** it shall be dealt with as per the prevailing guidelines.

**B. APPLICATIONS FOR GRANT OF LICENCE:**

- i. Existing Applications where Sample has been submitted in the Laboratory/Test Report has been issued by the Laboratory may be processed as per the old Standard. However, if the Applicant is desirous of considering the Application as per the revised Standard, a declaration may be obtained from the Applicant to that effect and the Application may be processed accordingly. An undertaking shall from such Applicants also be obtained that if the sample fails while considering the provisions of the revised Standard, Licence will not be granted by BIS as per the old version.
- ii. Applications which are recorded henceforth may be processed as per the old Standard or the revised Standard. Processing of Applications as per the old Standard shall be permitted only up to **27 March 2024** and for such cases Applicant shall give a declaration that they will implement the revised Standard by **28 March 2024**.
- iii. Beyond **28 March 2024** no Licence shall be granted as per the old Standard.

**C. CHANGE IN SCOPE OF LICENCE:**

- i. For change in scope of licence, the relevant provisions as given above for Applicants shall apply.
- ii. However, processing of such applications for change in scope of licence as per the old Standard shall be permitted only upto the date of implementation of the revised Standard or upto **28 March 2024** whichever is earlier.

6. The above guidelines come into force with immediate effect.

**Aditya Das**  
**Sc. D**

**Head (CMD-2)**  
**DDG (Certification)**